

## **REMARKS**

This amendment and these remarks are responsive to the non-final Office action dated November 15, 2004, and are being submitted under 37 C.F.R. § 1.111. Claims 1-31 and 43 are pending in the application. In the Office action, the Examiner (1) rejected claim 13 as being insufficiently enabled under 35 U.S.C. § 112, first paragraph; (2) rejected claims 1, 2, 5-8, 12, 14-19, 22-24, 27, 28, 30, 31, and 43 under 35. U.S.C. § 102 (as being anticipated by U.S. Patent No. 5,429,641 to Gotfried); and (3) objected to claims 3, 4, 9-11, 13, 20, 21, 25, 26, and 29 (as being dependent upon a rejected based claim). Applicants traverse the rejections, contending that the rejected claims are neither anticipated nor obvious. Nevertheless, to expedite the issuance of a patent, and to more particularly point out and distinctly claim aspects of the invention that applicants would like to patent now, applicants have amended claim 1 to include the limitation of claim 3 (which was objected to), and have canceled claim 3, without prejudice. In addition, applicants have added new claims 44-55, including new independent claims 44 and 52, which include all of limitations of claims 4 and 10, respectively (each of which was objected to). Furthermore, applicants have presented arguments showing that rejected claim 13 is sufficiently enabled and that the rejected claims are not anticipated or obvious. Accordingly, applicants respectfully request reconsideration of the rejected claims, and prompt issuance of a Notice of Allowability covering claims 1, 2, 4-31, 43, and 44.

***I.      Information Disclosure Statement***

Applicants filed an Information Disclosure Statement (IDS) on February 14, 2005, and respectfully ask the Examiner to consider the IDS, and the references cited therein, in reviewing this communication.

***II.     Objection to the Abstract***

The Examiner objected to the abstract, stating that "it lacks a sufficient summation of the invention." Applicants traverse this objection. However, to reduce the number of issues under consideration, and to expedite the issuance of a patent, applicants have amended the abstract to describe amended claim 1. The addition of claim 1 to the abstract is for illustration, and is not intended, and should not be interpreted, to limit or define the entire scope of the invention. Applicants believe the amended abstract should overcome the objection.

***III.    Claim Rejection – 35 U.S.C. § 112***

The Examiner rejected claim 13 under 35 U.S.C. § 112, first paragraph, as being insufficiently enabled. In particular, the Examiner stated that this claim "contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." Applicants strongly disagree: both the drawings and the associated text of the application enable the subject matter of claim 13. Claim 13 is a dependent claim directed to a guide device:

13. (Original) The guide device of claim 1, wherein the guide portion is configured to be movable into engagement with the bone so that the bone is pushed toward the bone-repair device.

Figures 2 and 5, for example, illustrate an exemplary guide portion 76 of a guide device 54 that meets the limitations of claim 13:

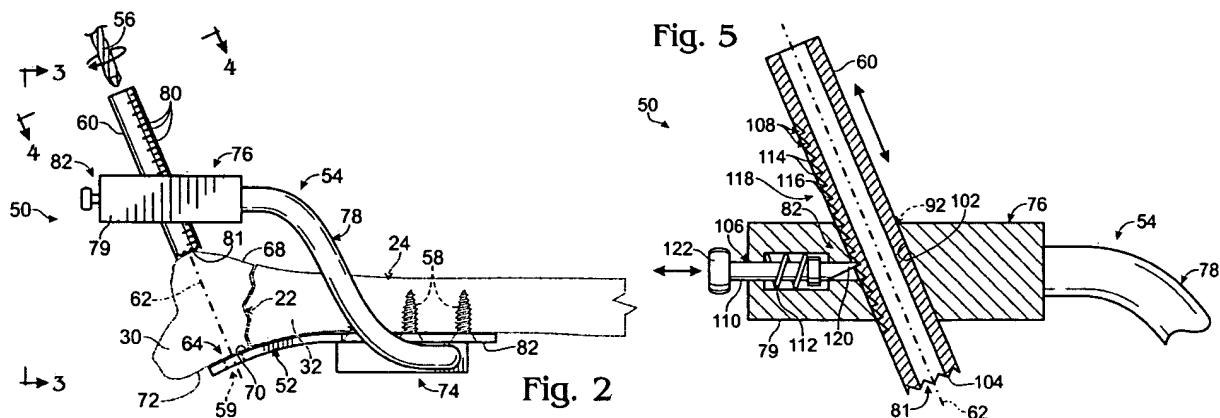


Figure 2 shows guide portion 76 (and particularly a guide element 60 thereof) disposed in engagement with bone 24 and opposing bone-repair device 52. Figure 5 shows how the guide portion is movable along axis 62, toward or away from bone (as indicated by the double-headed arrow parallel to axis 62). One of skill in the art would be able to understand how motion of the guide element into engagement with the bone would push the bone (and particularly a fragment (30) of the bone (see Figure 2)) toward the bone-repair device.

The specification includes significant description of guide portion (and particularly guide element 60) movement against bone, for example, in the following passages from the application:

(page 14, lines 6-16):

In some embodiments, guide element 60 may have restricted movement in one or both directions parallel to guide axis 62. Restricted movement of guide element 60 may be governed by a detent mechanism 82. The detent mechanism may be any mechanism configured to restrict movement of a guide element relative to the coupling portion and/or other regions of the guide portion. In some embodiments, the detent mechanism may permit axial movement of guide element 60 toward the bone-repair device, but restrict axial movement away from the bone-repair device. This may permit a guide element to apply a force on a bone (or bone portion) toward a bone-repair device, for example, parallel to a guide axis, to urge the bone (or portion) toward the bone-repair device. The

detent mechanism also may be releasable to permit axial movement of the guide element in both directions.

(page 18, line 16 to page 19, line 14):

Detent mechanism 82 may be configured to allow or restrict movement of guide element 60. The detent mechanism may include a movable catch 106 and an array of engagement sites 108 for the catch. The catch may be configured, for example, as a pin 110 that is biased in position using a biasing mechanism, such as spring 112. Engagement sites 108 may be defined by a series of projections 114 and/or depressions 116, for example, forming a set of teeth 118. Teeth 118 and/or a distal end 120 of the pin may be configured to be asymmetric in profile, so that movement of guide element 60 away from the bone is restricted and movement toward the bone is permitted. Pin 110 may be movable within frame 79 between engaged and released positions. In the engaged position, shown in the present illustration, distal end 120 of the pin may engage teeth 118 to restrict movement of guide element 60 away from the bone, parallel to guide axis 62, but to permit movement of the guide element toward the bone. Pin 110 also may include a handle 122 that may be operated with a tool or manually, without tools, to move pin 110 out of engagement with teeth 118, thereby releasing guide element 60 so that it is permitted to slide in one or both axial directions.

In operation, guide element 60 may be moved into engagement with a bone so that serrated distal end 81 applies a force on the bone. The force may be directed toward bone plate 52. Thus, guide element 60 and bone plate 52 may form a clamp that holds a bone fragment or portion in position between the guide portion and the bone plate. Detent mechanism 82 may be inactivated, such as by retraction of pin 110, to release the clamp, which may permit movement of the guide element away from the bone, thus releasing intervening bone.

Accordingly, applicants believe that claim 13 if fully enabled by both the drawings and the text of the specification and thus meets the requirements of 35 U.S.C. § 112, first paragraph (among others). Therefore, rejection of claim 13 under 35 U.S.C. § 112, first paragraph, should be removed.

#### **IV. Claim Rejections – 35 U.S.C. § 102**

The Examiner rejected claims 1, 2, 5-8, 12, 14-19, 22-24, 27, 28, 30, 31, and 43 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,429,641 to Gotfried. Applicants traverse these rejections. Gotfried does not teach or suggest each of the elements of any of these claims. Nevertheless, to expedite the issuance of a patent, and to more particularly point out and distinctly claim aspects of the invention that applicants

would like to patent now, applicants have amended independent claim 1 to include all the limitations of “objected to” claim 3. Furthermore, applicants have presented arguments below showing that each of these rejected claims should be allowed.

### **Claims 1-14**

In the Office action, the Examiner objected to claim 3 as being dependent upon a rejected base claim (claim 1), but indicated that it would allowable if rewritten in independent form. Applicants have canceled claim 3, without prejudice, and amended claim 1 to correspond to claim 3 rewritten in independent form:

1. (Currently amended) A guide device for guiding at least one of a hole-forming tool and a fastener to a bone-repair device, comprising:
  - a coupling portion configured to be connected to the bone-repair device adjacent a first surface of a bone; and
  - a guide portion connected to the coupling portion and configured to guide the at least one hole-forming tool and fastener into the bone and then to a predefined position of the bone-repair device,  
wherein the guide portion is configured to be disposed adjacent a second surface of the bone that generally opposes the first surface on the bone.

Accordingly, amended claim 1 should be allowed. Dependent claims 2 and 4-14, which depend from claim 1, also should be allowed for at least the same reasons as claim 1. Applicants reserve the right to pursue claim 1, without amendment, at a later time.

### **Claims 15-27**

Independent claim 15 was rejected under 35 U.S.C. § 102(b) as being anticipated by Gotfried. Claim 15 is directed to a guide device:

15. (Original) A guide device for guiding at least one of a hole-forming tool and a fastener to a connective feature of a bone-repair device, comprising:
  - a coupling portion configured to be connected to the bone-repair device adjacent a bone; and
  - a guide portion connected to the coupling portion and configured to be disposed in a predefined relation to the bone-repair device so that the guide portion defines a guide axis extending from the guide portion, through the bone, and then to the connective feature of the bone-repair device.

Gotfried does not teach or suggest a guide portion connected to a coupling portion and defining "a guide axis extending from the guide portion, through the bone, and then to the connective feature of the bone-repair device," as required, in part, by claim 15.

Figure 2 of the present application, presented here in simplified form with some of the numbers and lead lines deleted, shows an example of a guide device 54 that meets the limitations of claim 15:

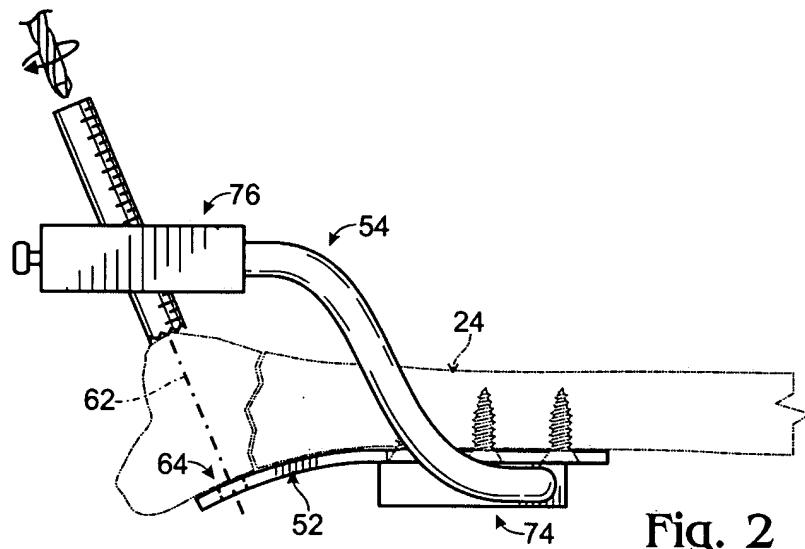
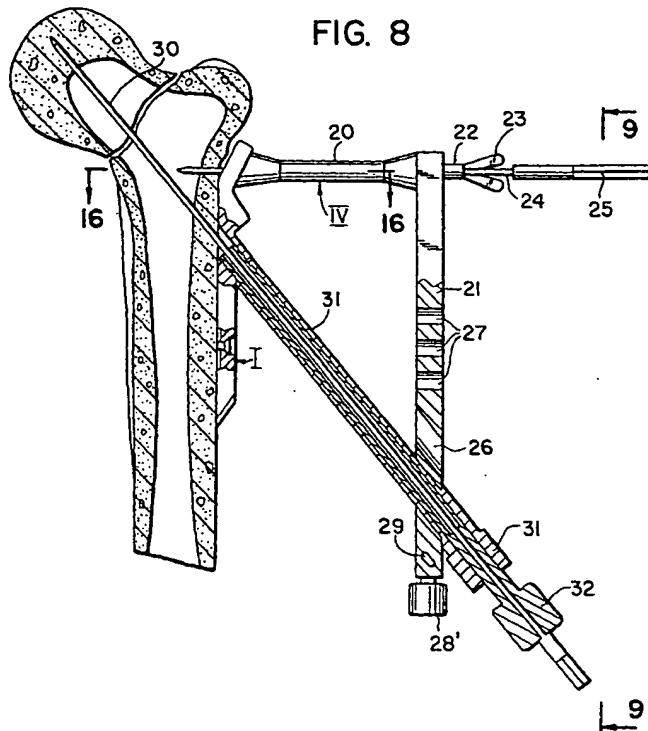


Fig. 2

In particular, the guide device includes (1) a coupling portion 74 configured to be connected to a bone-repair device 52 adjacent bone 24, and (2) a guide portion 76 connected to coupling portion 74 and configured to be connected in a predefined relation to bone 24 so that guide portion 76 defines a guide axis 62 extending from the guide portion, through bone 24, and then to a connective feature 64 of bone-repair device 52.

Gottfried relates to a connector plate for connection of fractured bones. Figure 8 shows the connector plate (indicated at "I") disposed on a fractured bone, and coupled

to auxiliary equipment for placement of a wire (and screws) through the plate and into the bone:



The auxiliary equipment includes an L-shaped connector arm (indicated at "IV") extending rightward from the plate, and then downward. The connector arm holds an outer tube 31 that extends through a bore of the connector arm into threaded engagement with the plate. The auxiliary equipment of Gottfried is structured to guide a wire, as shown here, or a screw, (1) from the outer tube, (2) through the plate, and (3) then into bone. However, the auxiliary equipment of Gotfried is not structured to guide a tool and/or fastener (1) from a guide portion, (2) through the bone, and (3) then to a connective feature of a bone-repair device, as required, in part, by claim 15. Accordingly, Gotfried teaches a structure that does not meet the functional limitations recited by claim 15.

In the Office action, in rejecting many of the claims, including claim 15, the Examiner asserted that the functional limitations in these claims does not distinguish them from the prior art. In particular, the Examiner stated:

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ 1964 (1987). The particulars of the bone plate are given no patentable weight.

The Examiner further stated:

Also [it] has been held that the recitation that an element is “adapted to” perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Applicants strongly disagree with these assertions related to functional limitations.

The MPEP (at §2173.05(g)) describes functional limitations as follows:

A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). *There is nothing inherently wrong with defining some part of an invention in functional terms.* (emphasis added)

Applicants have relied on functional limitations to define aspects of the claimed invention and distinguish it from the prior art. In particular, applicants have used functional limitations to recite functional attributes of the recited structure (i.e., the coupling portion and the guide portion) that are not taught or suggested by the prior art. These functional attributes do not necessarily relate to “the manner” in which the claimed guide device “is intended to be employed,” as asserted by the Examiner. Instead, they recite what the claimed elements can do (and what the prior art cannot). These functional attributes thus are provided necessarily by a structure and/or arrangement of the coupling portion and/or guide portion that is not in the prior art, as

exemplified by comparison of Figure 2 of the present application with Figure 8 of Gotfried.

To summarize, Gotfried does not teach or suggest all of the limitations of claim 15. Therefore, claim 15 should be allowed. Claim 16-27, which depend from claim 15, also should be allowed, for at least the same reasons as claim 15.

### **Claims 28-31**

Independent claim 28 was rejected under 35 U.S.C. § 102(b) as being anticipated by Gotfried. Claim 28 is directed to a system for fixing a bone:

28. (Original) A system for fixing a bone, comprising:  
a bone plate including a connective feature; and  
a guide device configured to guide at least one of a hole-forming tool and a fastener through the bone and then to the connective feature, including (1) a coupling portion configured to be connected to the bone plate, and (2) a guide portion connected to the coupling portion and configured to be disposed in a predefined relation to the bone plate so that the guide portion defines at least one guide axis intersecting the connective feature of the bone plate.

Gotfried does not teach or suggest a guide device configured to guide a hole-forming tool and/or fastener “through the bone and then to the connective feature” of a bone plate (as required, in part, by claim 28), for at least the same reasons as described above in relation to claim 15. Therefore, claim 28 should be allowed. Claims 29-31, which depend from claim 28, also should be allowed for at least the same reasons as claim 28.

### **Claims 43**

Independent claim 43 was rejected under 35 U.S.C. § 102(b) as being anticipated by Gotfried. Claim 43 is directed to a guide device:

43. (Original) A system for repairing a bone, comprising:  
means for defining, at least substantially external to the bone, a guide axis that extends through the bone; and  
means for directing a bone screw along the guide axis, through the bone, and then into threaded engagement with an opening of the bone plate.

Gotfried does not teach or suggest means for directing a bone screw along a guide axis “through the bone, and then into threaded engagement with an opening of the bone plate,” as required by claim 43, for at least the same reasons as described above in relation to claim 15. Therefore, claim 43 should be allowed.

**V. New Claims**

The current communication adds new claim 44-55. Exemplary support for the new claims is shown, without limitation, in the following table:

<b>New Claim</b>	<b>Original Claim</b>
44 (Independent)	(1)+4
45	5
46	6
47	7+8
48	10
49	11
50	12
51	13
52 (Independent)	(1+7+8)+10
53	5
54	11
55	22

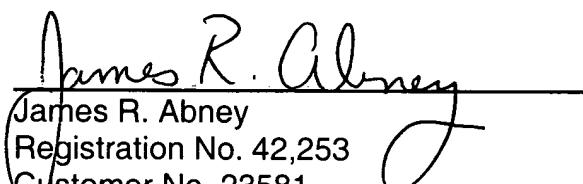
Independent claim 44 includes all the limitations of original claim 4 (and original claim 1, from which original claim 4 depended). Independent claim 52 includes all the limitations of original claim 10 (and original claims 1, 7, and 8, from which original claim 10 depended directly or indirectly). In the Office action, original claims 4 and 10 were objected to, but were indicated to be allowable if rewritten in independent form. Therefore, claims 44 and 52 should be allowed. Dependent claims 45-51 and 53-55, which depend, respectively, from claims 44 and 52, also should be allowed for at least for the same reasons as claims 45 and 52.

**IV. Conclusion**

Applicants believe that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, applicants respectfully request that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

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